

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY)	MDL NO. 1456
AVERAGE WHOLESALE PRICE)	
LITIGATION)	CIVIL ACTION: 01-CV-12257-PBS
)	
)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>)	Magistrate Judge Marianne B. Bowler
<i>Inc. v. Abbott Laboratories, Inc.,</i>)	
No. 06-CV-11337-PBS)	

**ABBOTT LABORATORIES INC.'S OBJECTIONS TO THE SPECIAL MASTER'S
ORDERS ON *IN CAMERA* REVIEW OF DOCUMENTS**

Over three years into this litigation, in which the Government seeks to make Abbott pay millions of dollars based on pricing the Government alleges was “false or fraudulent,” the Government still refuses to come clean as to what it knew, and when it knew it, as to the pricing for the kinds of drugs at issue in this case. Besides the countless documents it spoliated in the last decade and a half (and thus cannot produce) (*see* Dkt. No. 6097), the Government continues to withhold numerous documents based on a massively overbroad assertion of the “deliberative process privilege.” It is extremely unfair for the Government to claim it was misled, and then deny Abbott the very evidence that would debunk that claim.

When last the parties were before the Court on this issue, on a tiny subset of documents, the Government wildly claimed that the documents Abbott sought were irrelevant. This Court disagreed and, following an *in camera* review, ordered 75% of them produced. Later, Magistrate Bowler ordered that 134 other documents—and the Government’s wide invocation of the deliberative process privilege to suppress witness testimony—be submitted to a Special Master. The parties agreed that the Special Master’s ruling would be directly reviewable by this Court as the ruling of a Magistrate Judge. (Dkt. No. 6170.)

The Special Master was able to overrule all of the Government's specious objections as to the deposition testimony given the Government's essentially non-existent support for those objections. Unfortunately, however, the Special Master was ill-equipped (as he candidly admitted) for the more difficult task of reviewing the 134 documents the Government submitted. As he put it, he was (understandably) hobbled in his review of the documents by his "little connection and familiarity with this very complex case." (June 22 Order at 5 n.2.) It is therefore disturbing that the Special Master (in stark contrast to this Court) ordered only one of the Government's 134 documents produced—repeatedly making broad statements about irrelevance, even though he admitted he was at best sketchy on the contours of relevance in this case. It is also troubling that the Special Master failed to analyze any alleged hardship to the Government in producing these documents, despite this Court's clear admonition in its November 5, 2008 Order that "it is hard to imagine that disclosure" of the old documents at issue "will chill future timid government employees." (Dkt. No. 5665 at 17.)

While Abbott has done its best to avoid burdening this Court with the Government's well over-broad assertions of the deliberative process privilege, this Court's intervention is now required. Abbott is not challenging all of the Special Master's document rulings; these objections target only a small, crucial subset of 34 documents, which Abbott knows—either from unredacted text or other documents surrounding the withheld material—are particularly relevant. Abbott's need for this evidence, in this case where the Government is suing for alleged "fraud," is undeniable. It would be needlessly wasteful for all involved to go through trial and appeal, only to have to redo all of it because these key documents were not timely produced. Accordingly, pursuant to Fed. R. Civ. P. 72(a), Abbott respectfully requests that its objections be sustained and, following an *in camera* review, that these documents be produced.

PROCEDURAL BACKGROUND

A. The Court's Prior Proceedings.

On July 24, 2008, the Court held oral argument on Abbott's motion to certify for interlocutory appeal certain prior rulings on the deliberative process privilege. The Court made clear that evidence relating to the Government's knowledge of and response to drug spreads was of "paramount" importance to this case. (*See* July 24, 2008 Hrg. at 4-6.) The Court directed the Government to re-review its files and produce any document that might show "some sort of government knowledge and acquiescence in or approval" of mega-spreads for infusion and inhalation products, including evidence of "cross-subsidization or the like." (*Id.* at 17, 20.) The Government was to "err on the side of, obviously, showing anything." (*Id.* at 26.)

On September 15, 2008, the Government produced twelve more documents for *in camera* review, but argued that "none of them have probative value with respect to the claims and defenses at issue in this case." (Dkt. No. 5551 at 2.) The Court's November 5, 2008 Order on these documents disagreed with that argument a full 75% of the time. (Dkt. No. 5665 at 17-20.)

On November 11, 2008, Defendants moved for appointment of a Special Master to conduct a more thorough review of the Government's deliberative process withholdings. (Dkt. Nos. 5675 & 5676.) Defendants asked for an *in camera* review of 184 prioritized documents not already submitted to the Court. Defendants also suggested that a Special Master might review another 42 documents already submitted for *in camera* review, as well as Abbott's challenges to the Government's deliberative process privilege assertions at depositions.

The Court raised Defendants' request for a Special Master during a November 13, 2008 status conference, and implored the Government to take a more reasoned approach. Among other things, the Court criticized the Government's failure to produce "factual recitations," "post-policy" documents, "old" documents, or communications "outside the agency." (*See* Nov. 13,

2008 Hrg. at 15-18.) The Court also criticized the sufficiency of the Government's broad-based declarations of the alleged harm that would be caused by disclosure of (usually old) documents, observing: "[Y]ou didn't give me a declaration that went document by document . . . [T]hey were broad-sweeping, the end of the Republic if these are produced." (*Id.* at 40.)

Subsequent to that hearing, the Government did produce 115 of the 184 documents prioritized by Defendants. But many were redacted. Worse, the Government's productions were highly selective. It produced some documents on subjects of particular interest to Defendants (*e.g.*, the so-called "DOJ AWP" effort),¹ but continued to withhold others on the same subjects. (*See infra* at 8-14.) Indeed, all told, the Government continued to withhold all or portions of 75 of the 184 documents, including documents described as follows on the Government's privilege logs:

- April 26, 1996 documents relating to a draft CMS rule to move to actual acquisition cost which "[d]iscuss[] alternative reimbursement mechanisms and the pros and cons of such policies." (HHC902-0035-0052, HHC902-0053-0055);
- A 2001-2002 "[d]iscussion of numerous alternative reimbursement mechanisms for Medicare-covered drugs" which "[i]ncludes handwritten notes listing and describing many of the possible alternative reimbursement mechanisms (*i.e.*, brainstorming material"). (HHC902-0187-0201);
- A June 28, 1990 "[m]emorandum in response to request for clarification of HCFA policy relating to Estimated Acquisition Cost (EAC) and rebates from manufacturers. Memo clarifies the language in the regulation in light of the requesting party's initial understanding." (HHC902-0646-0651);
- An undated "Draft memo" described as "Subject: Determination of Medicaid Prescription Drug Estimated Acquisition Cost (EAC); Discussing generally, state plan amendment requests that propose to change reimbursement methodology and how to analyze these state plans." (HHC904-0603-0606); and
- Undated "Notes" described as "Handwritten notes re problems with AWP." (HHD920-2223-2224).

¹ As detailed in Abbott's Memorandum in Support of its Motion for Partial Summary Judgment, and other filings, the "DOJ AWP" effort plays an important role in this litigation. (*See* Dkt. No. 6186 at 6-7.)

On December 31, 2008, Defendants filed a Motion to Compel Relief on Outstanding Deliberative Process Privilege Issues, summarizing outstanding deliberative process issues and reiterating Defendants' request for a Special Master. (Dkt. Nos. 5812 & 5813.) On March 30, 2009, Magistrate Judge Bowler granted Defendants' motion for a special master, appointing Honorable Allan van Gestel of JAMS. (*See* Dkt. No. 5985.)² Her Order directed the parties to advise the Court whether they would stipulate to the review to be afforded the Special Master's findings. (Dkt. No. 5985 at 4.) The parties jointly stipulated "that the decision(s) of the Special Master, for the purposes of Fed. R. Civ. P. 53(f), shall be deemed final as if made by the Magistrate Judge." (Dkt. No. 6170 at 1-2.)

In addition to the six categories of evidence outlined in the March 30 Order, the parties stipulated that the Special Master could include in his review eight (8) "Late Arrival" documents produced after the close of fact discovery in redacted form. (*Id.* at 2.)

B. The Special Master's Rulings.

On June 22, 2009, after a short scheduling conference call among the parties and the Special Master, Judge van Gestel issued a Memorandum and Order on *In Camera* Review of Documents (the "June 22 Order") (Ex. A). Judge van Gestel did not request oral argument on any of the outstanding issues. On June 29, 2009, Judge van Gestel issued a Supplemental Memorandum and Order on *In Camera* Review of Documents and Deposition Testimony (the "June 29 Order") (Ex. B). The June 29 Order provided rulings on five documents not covered by the June 22 Order, as well as on the deposition challenges. With the exception of item 3 (a CMS

² Magistrate Bowler's Order identified the following six different categories of evidence subject to the Special Master's review: (1) the 75 remaining documents prioritized by Defendants; (2) the 42 documents submitted for *in camera* review on December 4, 2007 and June 3, 2008; (3) the entirety of a CMS decision memorandum; (4) the minutes of entrance and exit conferences for five Office of Inspector General reports of particular interest to Defendants (which have not been produced or logged by the Government); (5) any documents designated by Defendants from the files of Medicare carriers; and (6) 23 instances where Government counsel asserted the deliberative process privilege at deposition. (*Id.* at 3.) These Objections are focused primarily on the first category, as well as the eight "Late Arrival" documents.

“decision memorandum”), the June 22 and June 29 Orders denied Defendants’ motion to compel as to documents across-the-board. The Judge did, however, grant Abbott’s motion to compel as to the Government’s improper invocation of the deliberative process privilege in depositions.

Critically, as to the documents, Judge van Gestel’s June 22 Order included a candid—but troubling—“caveat”:

The caveat is the obvious: reviewing the documents submitted was a particularly dense project, intellectually and otherwise, *especially for someone with as little connection and familiarity with this very complex case as your Special Master.*

(June 22 Order at 5 n.2) (emphasis added).

For some documents, the Special Master did not consider the relevance question at all. In particular, for the eight “Late Arrivals,” Judge van Gestel simply accepted the Government’s claim that these documents were “irrelevant.” (*See* June 22 Order at 16 (“Additionally, for the reasons stated above, the Special Master will not get involved in the relevance issues with these documents.”).)³ Furthermore, Judge van Gestel did not render decisions on four specific documents because he was under the mistaken belief that the Government had properly asserted the attorney-client privilege or work product doctrine, rather than the deliberative process privilege, for these documents. (*See* June 22 Order at 8, 10.)

The Special Master’s decisions on the individual documents provide very little detail on why he concluded the Government could continue to withhold the documents in their entirety—without the need to at least produce segregable factual information. Rather, the Special Master used uniform language to describe his conclusions, namely, that the documents “seem hardly relevant to the issues in the underlying case and the balance between the public interest in the

³ As produced *in camera* to the Special Master, the eight “Late Arrivals” have the following Bates numbers: HHD831-000001-000003; HHD831-000004-000006; HHD831-000007-000012; HHD832-000001-000007; HHD832-000008-000011; HHD832-000032-000037; HHD832-000012-000031; HHD832-000038-000041. (*See* Ex. C, 6/24/09 Ltr. from J. Draycott to Hon. van Gestel.)

protection of the deliberative process and the Defendants' particularized need for the information in this case falls clearly on the side of the Government." (June 22, 2009 Order at 6-9, 11-12, 15-16.) Because there is little, if any, discussion of the subject-matter of most documents, there is rarely any discussion of why the document is purportedly irrelevant. Nor is there any discussion of the harm of disclosing the individual documents.⁴

ARGUMENT

A magistrate judge's discovery ruling will be set aside if it is "clearly erroneous or contrary to law." *See* 28 U.S.C. § 636(b)(1)(A); *In re Admin. Subpoena Blue Cross Blue Shield of Massachusetts*, 400 F. Supp.2d 386, 388 (D. Mass. 2005). That standard is easily met here.

I. THE COURT SHOULD OVERRULE THE SPECIAL MASTER'S DECISION AS TO 34 OF THE 134 DOCUMENTS INCLUDED IN THE *IN CAMERA* REVIEW.

A. The Special Master's Sweeping Findings Did Not Appropriately Apply The Balancing Test.

The deliberative process privilege has no place in this case, where a Government agency-plaintiff seeks hundreds of millions of dollars in alleged "overpayments" made, knowingly, by that agency. *See Ghana Supply Comm'n v. New Eng. Power Co.*, 83 F.R.D. 586, 593-94 (D. Mass. 1979) ("the great weight of authority holds that fairness to the defendant requires the government to make available all information relevant to the defense") (collecting cases); *Dep't of Econ. Dev. v. Arthur Anderson & Co.*, 139 F.R.D. 295, 299 (S.D.N.Y. 1999) ("Where adjudication of fraud claims turns upon issues of knowledge, reliance, and causation, direct evidence of the deliberative process is irreplaceable.").⁵

⁴ On July 1, 2009, Abbott filed its Unopposed Motion for Extension of Time to File Objections to the Special Master's Order on *In Camera* Review of Documents. (Dkt. No. 6239.)

⁵ *See also United States v. Ernstoff*, 183 F.R.D. 148, 153 (D.N.J. 1998) ("courts have severely restricted the use of the privilege by government agencies"); *Resolution Trust Corp. v. Diamond*, 773 F. Supp. 597, 605 n.7 (S.D.N.Y. 1991) (FTC's role as plaintiff "tends to open the door to discovery of RTC's decision-making process"); *United States v. Hooker Chems. & Plastics Corp.*, 123 F.R.D. 3, 12 (W.D.N.Y. 1988) ("Perhaps most importantly, the government asserting the privilege in this case is a party to the litigation.").

While the Court has thus far declined to follow *Ghana* and *Department of Economic Development*, and has instead adopted the “balancing test” typically used outside the context of Government-initiated litigation for this case (Dkt. No. 5665 at 8-10),⁶ at a minimum the privilege should be strictly construed here—as this Court’s November 5, 2008 Order requiring production of eight of twelve documents implicitly acknowledged. Indeed, in that order, the Court found that Defendants’ need for documents outweighed any Government interest for six of the twelve documents. (Dkt. No. 5665 at 17-20.) In making its determinations, the Court observed, among other things, that “it is hard to imagine that disclosure” of old documents “will chill future timid government employees.” (*Id.* at 17.) Except for documents the Court found were completely irrelevant, the Court ordered production.

By contrast, the Special Master ordered production of just one of the 134 documents included in his *in camera* review. This result is remarkable because most of the documents included in the Special Master’s *in camera* review, and all of the documents focused upon here, are similar in substance to the twelve documents previously reviewed by this Court, including documents relating to (a) recommendations to move to an acquisition cost-based reimbursement model (HHD816-0025-0027, HHD816-0028), (b) the so-called “DOJ AWP’s” (HHD809-0005-0013, HHC902-0251-0258), (c) the Government’s knowledge of spreads (HHD816-0020-0021, HHD809-0080, and HHD919-0022), and (d) issues of provider lobbying and cross-subsidization (HHD816-0029). (Dkt. No. 5665 at 17-20.)

The only plausible reasons for this stark difference are a fundamental difference between this Court and the Special Master in applying the balancing test, and the Special Master’s

⁶ In conducting the balancing test, courts consider the following factors: (i) the relevance of the evidence sought be protected; (ii) the availability of other evidence; (iii) the “seriousness” of the litigation and the issues involved; (iv) the role of the government in the litigation; and (v) the possibility of future timidity by government employees who will be forced to recognize that their secrets are violable. *Id.* at 9 (citing *In re Franklin Nat’l Bank Sec. Litig.*, 478 F. Supp. 577, 583 (E.D.N.Y. 1979)).

professed inexperience with the complexities of these cases. (June 22 Order at 5.) For example, while this Court has been skeptical of the Government's professed harm (*see* Nov. 13, 2008 Hrg. at 40 ("[Y]ou didn't give me a declaration that went document by document . . . [T]hey were broad-sweeping, the end of the Republic if these are produced."); Dkt. No. 5665 at 17), there is no particularized discussion of this issue in the Special Master's Orders. Instead, the Special Master appears to have simply accepted the Government's "vague, general and conclusory statement[s] as to why the confidentiality of the listed documents should be maintained," which was improper. *Pac. Gas & Elec. Co. v. United States*, 71 Fed. Cl. 205, 209 (2006). Nowhere has the Government ever attempted to detail what harm would arise from disclosure of particular documents. (*See* Dkt. No. 5810 at 5-6.)

Nor, as the caveat in the June 22 Order admits, did the Special Master have a firm handle on the potential relevance of the documents. A telling example concerns the document at HHC902-0214-0244. This document concerns the "DOJ AWP" effort, and is replete with factual information critical to litigating this case—including statements that "a dilemma arises from the fact that delivery systems have developed around overpriced drugs" and provider assertions that "a high profit margin on drugs is necessary to cross-subsidize costs that are underfunded." (Ex. D.) This Court reviewed an earlier draft of this document (HHD809-0005-0013) (Ex. E) in its own *in camera* review, and ordered production. The Court observed that the document was "primarily factual" and, in any event, defendant's need outweighed the government's interest. (Dkt. No. 5665 at 5.) Abbott now has HHC902-0214-0244 because the Government produced it after the Court's November 5, 2008 Order.

Although it was already produced by the Government, HHC902-0214-0244 was included in the Special Master's review because the document was part of an earlier *in camera*

submission. Notably, however, the Special Master's ruling on this key document was 180 degrees different from this Court's ruling on a very similar document. (Dkt. No. 5665 at 17-18; HHD809-0005-0013.) The Special Master found that "the balance between the public interest in the protection of the deliberative process and the Defendants' particularized need for the information in this case falls clearly on the side of the Government." (June 22 Order at 12.) The Special Master did not even require the Government to produce any of the extensive factual information contained in the document.

Furthermore, the Special Master did not consider the relevance of several significant documents included in his review. In particular, in its cover letter forwarding the "Late Arrival" redacted documents, the Government, citing *United States v. Lachman*, 387 F.2d 42, 54 (1st Cir. 2004), told the Special Master that the documents were "completely irrelevant." (Ex. F, 5/1/09 Ltr. from J. Draycott to Hon. van Gestel.) The Special Master seems to have simply accepted the Government's representation. (See June 22 Order at 16 ("Additionally, for the reasons stated above, the Special Master will not get involved in the relevance issues with these documents."); June 29 Order at 2-3.)

Finally, there is no evidence at all that the Special Master considered the role of the Government in this litigation, and the well-established rule that the deliberative process privilege should be strictly construed when the Government is the plaintiff in litigation. *See supra* at 7. The Special Master should have done so.

B. The Balancing Test Tips In Abbott's Favor On The 34 Documents Discussed Here.

Although Abbott believes the Court should order production of each of the 134 documents included the Special Master's *in camera* review (and trusts it has preserved its motion on all of these documents for appeal), these Objections are tailored to 34 documents of particular

interest. The documents and their privilege log descriptions are contained on the attached

Schedule 1.⁷ The documents relate to the following substantive categories:

- ***The “DOJ AWP” (and the related issue of how CMS interpreted AWP)*** (*documents 1-10*) (HHC901-0788-0789, HHD924-0009-0016, HHC901-1023-1028, HHD831-000001-000003; HHD831-000004-000006; HHD831-000007-000012; HHD832-000008-000011; HHD832-000032-000037; HHD832-000012-000031; HHD832-000038-000041);
- ***How CMS interpreted and applied the Medicaid “estimated acquisition cost” regulation, and its approval of state plans*** (*documents 11-13*) (HHC903-0103-0110, HHC904-0603-0606, HHC902-0646-0651);
- ***CMS’s proposed regulation in the mid-1990s to move to an acquisition cost-based reimbursement model for Medicare*** (*documents 14-18*) (HHC902-0053-0055, HHC902-0035-0052, HHC902-0271-0310, HHC902-0059-0062, HHC902-0017-0018);
- ***Minutes from certain entrance exit conferences for OIG reports relating to drug pricing and reimbursement*** (*documents 19-25*) (HHD900-1065-1067, HHD900-1122, HHD900-2274, HHD911-0354, HHD911-2013-2039, HHD926-0056-0061; HHC903-0599-0601);
- ***Other documents concerning Medicare and Medicaid drug payment policy, including cross-subsidization*** (*documents 26-31*) (HHD920-2223-2224, HHC902-0187-0201, HHD954-0011-0012, HHD929-00028-0029, HHC904-0182-0191, HHD832-000001-000007); and
- ***Certain documents found in the files of Medicare carriers*** (*documents 32-34*) (AWQ917-0167-0169, AWQ917-0053-0064, and AWQ917-0114-0128).

DOJ AWP. For the reasons discussed in Abbott’s Memorandum in Support of its Motion for Partial Summary Judgment, the documents related to the DOJ AWP effort are integral to this case for multiple reasons. (*See* Dkt. No. 6186 at 6-7.) The Court has already compelled production of one DOJ AWP document the Government withheld under the deliberative process privilege. (Dkt. No. 5665 at 17-18.) Moreover, the Government’s principal argument on these documents—that they are “irrelevant” under *United States v. Lachman*, 387

⁷ To facilitate the Court’s review of these documents, Abbott suggests that the Government submit to the Court, or be ordered to submit, the 34 documents listed on Schedule 1 using the “#” identifier contained in the first column of Schedule 1.

F.3d 42, 54 (1st Cir. 2004) because personal opinions of agency employees are not relevant to “any interpretive issue relating to a federal regulation” (*see* Ex. F)—is seriously flawed. How CMS itself interpreted the term “average wholesale price” during the relevant time period (which discovery has shown to be different from the DOJ’s current litigating position and *amicus* brief), and the impact that interpretation had on CMS’s response to reports of “mega-spreads,” are critical issues. CMS’s understanding of how the industry as a whole, including drug manufacturers, understood the term “average wholesale price,” is also quite relevant.

Lachman does not hold that the universe of relevant and *discoverable* evidence regarding how a government agency interpreted a statutory or regulatory provision at issue in a fraud case is limited to the contents of the Federal Register. This is particularly true when, as here, evidence suggests Government entities have *changed* or have different interpretations on the provision at issue—the term “average wholesale price.”⁸ For instance, if the materials note or imply that the term “average wholesale price” is ambiguous and subject to different interpretations, that is certainly relevant to the Defendants’ defenses, including (for example) the questions of falsity and *scienter*. *See Safeco Ins. Co. of Am. v. Burr*, 127 S. Ct. 2201, 2216 n.20 (2007) (“Where, as here, the statutory text and relevant court and agency guidance allow for more than one interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator.”).

Given the importance of the DOJ AWP, it is difficult to believe that documents which discuss this subject have no relevance to this case. Indeed, it is practically these same “revised”

⁸ (E.g., compare CMS Response to 1998 OIG Report, *Are Medicare Allowances for Albuterol Sulfate Reasonable?* (OEI-03-97-00292, Aug. 1998) at A-2 (“The AWP is a price that is essentially established by the industry, similar to the sticker price on a vehicle. It is HCFA’s belief that AWP does not accurately reflect the true reimbursement for this product [albuterol sulfate], but rather is an inflated number. *As long as HCFA is required to use AWP*, which is essentially retail, we will continue to pay more than other payers.”) (emphasis added) (Ex. G, with HHD340-0031-0034 (“*Finally, we also have received a revised opinion from [Office of General Counsel] indicating that HCFA can require carriers to use the DOJ data, even without rule making.* This is because the data is characterized by DOJ as more accurately reflecting average wholesale prices.”) (italics in original) (Ex. H).)

prices that form the foundation of the Government’s entire damages case against Abbott. It is not plausible to suggest—particularly given what Abbott has already seen—that documents which discuss the “pros and cons” (*e.g.*, HHD831-000001-000003, HHD832-000032-00037) and the “problems” and “issues” (HHD832-000008-000011) of these prices are irrelevant.

EAC Regulation and State Plans. Likewise, any documents related to how CMS interpreted and applied the Medicaid “estimated acquisition cost” (EAC) regulation, and approved state plans setting forth drug payment rates, are presumptively relevant. There is no dispute that EAC and state payment rates have been key issues in both fact and expert discovery. Both sides have experts whose principal opinions focus on these very issues. Furthermore, the documents in this category are very old. HHC903-0103-0110 (of which the Government is still withholding HHC903-0105-0107) is dated August 11, 1988. HHC902-0646-0651 is dated June 28, 1990. The Government’s log does not provide a date for HHC904-0603-0606, but it appears old as well. Given the age of these documents, “it is hard to imagine that disclosure will chill future timid government employees.” (Dkt. No. 5665 at 17.)

CMS Acquisition Cost Proposal. Documents relating to CMS’s proposals in the mid-1990s to move to an acquisition cost-based reimbursement structure for Medicare are equally relevant. Similar to the DOJ AWP, these documents concern the “pros and cons” of the very sort of “alternative reimbursement method” that the Government now seeks to impose retroactively through litigation. (HHC902-0035-0052, HHC902-0271-0310, HHC902-0059-0062). Moreover, the documents are all over a decade old, and there has been no showing of any harm caused by disclosure.

OIG Files. These Objections focus on a very discrete number of OIG files, in particular certain exit conferences for OIG reports that for the most part specifically involve the drugs at

issue.⁹ As described in prior briefing (*see* Dkt. No. 5676 at 13-16), Abbott believes documents summarizing the entrance and exit conferences are important, as they relate to how CMS reacted to the “mega-spreads” evidence collected by OIG. These documents are also old. The two most recent of these documents are dated in 2000, while the remainder were created over a decade ago. Again, the Government has made no showing of individualized harm from disclosure.

Other Medicare and Medicaid Policy Documents. The privilege descriptions for the other documents identified above demonstrate that those documents are relevant to the issues raised in this case. For example, although HHD929-0028-0029 and HHD832-000001-000007 are dated in 2003, that does not necessarily mean they are irrelevant. In fact, the 2003 decision to exempt infusion drugs administered through durable medical equipment (drugs like vancomycin) from the new ASP methodology in order to continue paying based on AWP and providing a cross-subsidy (*see* Dkt. No. 6186 at 6 n.5) is quite relevant. So are documents that discuss the impact of lowering drug ingredient payments. This is true regardless of whether such documents were drafted after 2001.

Carrier Documents. Finally, consistent with its previous statements, the Court should order the Government to produce documents that were collected from outside the agency. (Nov. 13, 2008 Hrg. at 16 (“there were ones that were from outside the agency, I forget some carrier. They weren’t even protected”); 18 (“So any carrier documents shouldn’t be [withheld].”).) These would include three prioritized documents found in the files of Medicare carriers.

⁹ As discussed in Abbott’s Memorandum in Support of its Motion for Spoliation and For Sanctions (Dkt. No. 6097 at 16-18), the Government has destroyed the entrance and exit conference minutes for many of the OIG reports that specifically involve the drugs at issue.

C. The Government Should Not Be Permitted To Selectively Withhold Allegedly Deliberative Process Documents.

Courts are loathe to permit litigants to selectively waive the privilege over documents covering the same subject matter. “Were the law otherwise, the client could selectively disclose fragments helpful to its cause, entomb other (unhelpful) fragments, and in that way kidnap the truth-seeking process.” *In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 24 (1st Cir. 2003); *see also Tardiff v. Knox County*, No. 07-10-P-H, 2007 WL 2413033, at *2 (D. Me. Aug. 21, 2007) (“However, ‘[i]t is well accepted that waivers by implication can sometimes extend beyond the matter actually revealed. Such waivers are almost invariably premised on fairness concerns.’ . . . If the judicial disclosure demonstrates a choice by the client to put privileged communications at issue, ‘only the revelation of all related exchanges will allow the truth-seeking process to function unimpeded.’”) (quoting *In re Keeper of Records*, 348 F.3d at 23-24).

Here, the Government voluntarily released the deliberative process privilege on numerous documents. The released documents cover the same subject matters as those documents it continues to withhold, including documents relating to the DOJ AWP (e.g., HHC902-0214-0244) (Ex. D)), the EAC regulation and CMS’s approval of state plans (e.g., HHC006-0299-0302 (Ex. I), HHC906-0558-0559) (Ex. J)), and CMS’s acquisition cost proposal (e.g., HHC902-0005-0016) (Ex. K)), among others. The Court should not permit the Government to selectively waive the privilege, as doing so impedes the truth-seeking process.

D. The Government Has Waived Any Privileges Applicable To Four Of The Documents.

The Special Master determined that he did not have jurisdiction to adjudicate Defendant’s challenge to four documents included in his *in camera* review (HHC901-1023-1028, HHC902-0648-0651, HHC903-0599-0601, HHD954-0011-0012) because those documents were

purportedly withheld under the attorney-client privilege or work product doctrine, not the deliberative process privilege.¹⁰ This came as a surprise to Abbott, since the privilege log entries for each these four documents indicate they were being withheld only under the *deliberative process* privilege. These entries say nothing about the attorney-client privilege or work product doctrine. (See Ex. L, attached log excerpts.)

When counsel for Abbott inquired to the DOJ about the discrepancy, counsel stated that he assumed the Special Master's determination was "based on the memorandum we filed when we submitted the docs in camera to the Court in December 2008 – See Dkt. No. 5750 at pp. 10, 11, and 15. The docs that you reference correspond to Tabs 2B, 2C, 2D, and 6A – which is the reference we used in the Govt's memorandum." (Ex. M). The Government's *December 2008* memorandum did argue these documents were protected by the attorney-client privilege or work product doctrine, but these statements were inconsistent with the privilege assertions in the Government's privilege logs.¹¹

The Government waived any attorney-client privilege or work product doctrine that might have applied to these four documents by failing to assert those privileges timely or properly. See *Marx v. Kelly, Hart & Hallman, P.C.*, 929 F.2d 8, 12 (1st Cir. 1991) ("The burden is on the party asserting a privilege to do so in a timely and proper manner and to establish the existence and applicability of the privilege. Privilege claims may be raised as an objection to a specific documentary production request. See Fed. R. Civ. P. 34(b). But the assertion of

¹⁰ (See June 22 Order at 8 ("The next three documents are said by the Government to be protected from production by the attorney-client privilege and the work product doctrine. They do not raise issues under the deliberative process privilege. Consequently, because this Special Master was not directed to deal with anything other than the deliberative process privilege, no action was taken on these documents. They bear Bates Stamp Nos. HHC901 1023-1028, HHC902 0648-0651, HHC903 0599-0601."); 10 ("There remain two additional OIG documents. One bears Bates Stamp Nos. HHD954 0011-0012. It is withheld by the Government for attorney client privilege reasons. This Special Master, therefore, takes no action concerning it."))

¹¹ Because the Government did not associate Bates numbers for the documents submitted through its December 2008 memorandum, Abbott would have no way of knowing which of the numerous documents were included at what "Tabs" in the Government's *in camera* submission.

privilege must be timely and must also be accompanied by sufficient information to allow the court to rule intelligently on the privilege claim.”). The Government’s pseudo assertion of these privileges in a December 2008 brief—well after the close of discovery—is neither timely nor consistent with the Federal Rules.

Should the Court not find a waiver, even on the merits these documents are clearly not privileged. (Abbott’s challenge is timely because Abbott only recently learned that the Government was asserting the attorney-client and work product doctrine as to these documents.) The implicated documents appear to relate to Government lawyers’ work as investigators and policy makers, not to the seeking and receiving of legal advice. *See Coastal Corp. v. Duncan*, 86 F.R.D. 514, 521 (D. Del. 1980) (noting that government attorneys often function primarily as policy-makers rather than as lawyers, and rejecting assertion of attorney-client privilege over documents). For example, the documents at HHC901-1023-1028 and HHD954-011-0012 relate to Government lawyers’ work on the DOJ AWP’s, clearly a policy role. Indeed, it would greatly enhance the truth-seeking process in this case for the Court to order production of all factual material related to Government lawyers’ work on the DOJ AWP’s.

CONCLUSION

For the foregoing reasons, the Court should overrule the Special Master’s June 22 and 29 Orders on the 34 documents discussed in this memorandum and, following *in camera* review, order immediate production of these documents.

Dated: July 14, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

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/s/ David S. Torborg

David S. Torborg